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| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | | Compleat If Known | | |
| | | | Application Number | Filed Herewith | |
| | | | Filing Date | December 11, 2002 | |
| | | | First Named Inventor | German, Michael S. | |
| | | | Art Unit | Unassigned | |
| Examiner Name | Unassigned | | | | |
| Sheet | 1 | of | 3 | Attorney Docket Number | 023070-138122US |

| U.S. PATENT DOCUMENTS+ | | | | | |
|------------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number Number Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| 1.P. | AA | US-5,166,320 | 11/24/1992 | Wu, et al. | |
| | AB | US-5,670,347 | 09/23/1997 | Gopal | |
| | AC | US-5,766,899 | 06/16/1998 | Kuo, et al. | |
| | AD | US-5,792,751 | 08/11/1998 | Ledley, et al. | |
| | AE | US-5,827,703 | 10/27/1998 | Debs, et al. | |
| | AF | US-5,858,351 | 01/12/1999 | Podsakoff, et al. | |
| | AG | US-6,083,905 | 07/04/2000 | Voorberg, et al. | |
| | AH | US-6,093,392 | 07/25/2000 | High, et al. | |
| | AI | US-6,177,554 | 01/23/2001 | Woo, et al. | |
| 1.P. | AJ | US-6,265,387 | 07/24/2001 | Wolff, et al. | |

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|--------------------------|-----------------------|---------------------------|---------------------|--------------------------------|--|--|--------------------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | | Country Code ³ | Number ⁴ | | | | |
| 1.P. | AK | PCT | WO 91/06309 A1 | 05/16/1991 | Univ. Vanderbilt | | <input type="checkbox"/> |
| | AL | PCT | WO 93/19660 A1 | 10/14/1993 | Baylor College Medicine | | <input type="checkbox"/> |
| | AM | PCT | WO 94/29471 A1 | 12/22/1994 | Genetic Therapy Inc. | | <input type="checkbox"/> |
| | AN | PCT | WO 95/02698 | 01/26/1995 | Life Technologies Inc. | | <input type="checkbox"/> |
| 1.P. | AO | PCT | WO 96/30050 | 10/03/1996 | Univ. California | | <input type="checkbox"/> |

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| Examiner Signature | <i>Deanna P. Ma</i> | Date Considered | 10/12/06 |
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|--|---|--------------------------|--------------------|------------------------|-----------------|
| Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Complete If Known | | | |
| | | Application Number | Filed Herewith | | |
| | | Filing Date | December 11, 2002 | | |
| | | First Named Inventor | German, Michael S. | | |
| | | Art Unit | To be assigned | | |
| | | Examiner Name | To be assigned | | |
| Sheet | 2 | of | 3 | Attorney Docket Number | 023070-138122US |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|--------------------------|---|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| I.P. | AP | ABEMDROTH, et al., AN96126219, (1996). | |
| | AQ | ANDERSON, et al., "Human gene therapy," <i>Nature</i> , Vol. 392, pp. 25-30, (1998). | |
| | AR | <i>Biotechnology</i> , Vol. 10, pp. 132-136, (1992). | |
| | AS | BRUINSMA, et al., "Towards a new gene transfer system: Shock wave-mediated DNA transfer," pp. 102-103, (1994). | |
| | AT | GUMUCIO, D. L., et al., "Concerted Evolution of Human Amylase Genes," <i>Mol. Cell. Biol.</i> , Vol. 8, No. 3, pp. 1197-1205, (1988). | |
| | AU | HATZOGLU, M., et al., "Hepatic Gene Transfer in Animals Using Retroviruses Containing the Promoter from the Gene for Phosphoenolpyruvate Carboxykinase," <i>J. Biol. Chem.</i> , Vol. 265, pp.17285-17293, (October 1990). | |
| | AV | HICKMAN, et al., "Gene expression following direct injection of DNA into liver," pp. 1477-1483, (1994). | |
| | AW | HICKMAN, et al., "Therapeutic response produced by direct," p. 241, (1994). | |
| | AX | MELLITUS, <i>Journal of Endocrinology</i> , Vol. 143, pp. 339-343, (1994). | |
| | AY | OSBORN, L., et al., "Insulin Response of a Hybrid Amylase/CAT Gene in Transgenic Mice," <i>J. Biol. Chem.</i> , Vol. 263, No. 32, pp. 16519-16522, (November 1988). | |
| | AZ | PONDER, AN2000103902, (1999). | |
| | BA | SCHMID, R., et al., "Liposome Mediated in vivo Transfer Into Different Tissues of the Gastrointestinal Tract," <i>Zeitschrift fuer Gastroenterologie</i> , Vol. 32, No. 12, pp. 665-670, (1994). | |
| | BB | SOSA-PINEDA, et al., "The pax4 gene is essential for differentiation of insulin-producing beta cells in the mammalian pancreas," <i>Nature</i> , Vol. 386, pp. 399-402, (1997). | |
| | BC | TRIPATHY, S.K., et al., "Stable delivery of physiologic levels of recombinant erythropoietin to the systemic circulation by intramuscular injection of replication-defective adenovirus," <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 91, pp.11557-11561, (November 1994). | |
| I.P. | BD | VALERA, et al., "Regulated Expression of Human Insulin in the Liver of Transgenic Mice Corrects Diabetic Alterations," <i>Research Communications, US, FED. OF AMERICA SOC. FOR EXPERIMENTAL BIOLOGY</i> , BETHESDA, MD, (April 1994), Vol. 8., No. 8., pg. 440, paragraph 4, pg. 441, paragraph 2. | |

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| Examiner Signature | <i>Deanna R. [Signature]</i> | Date Considered | <i>10/12/02</i> |
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| | | | | Art Unit | To be assigned |
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| Sheet | 3 | of | 3 | Attorney Docket Number | 023070-138122US |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|--------------------------|---|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| 1.P. | BE | VERMA, et al., "Gene therapy-promises, problems and prospects," <i>Nature</i> , Vol. 389, pp. 239-242, (1997). | |
| 1.P. | BF | YAMADA, et al., "In vivo identification of a negative regulatory element in the mouse rennin gene using direct gene transfer," <i>J. Clin. Invest.</i> , Vol. 96, pp. 1230-1237, (1995). | |

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| Examiner Signature | <i>Thomas P. No</i> | Date Considered | <i>10/12/08</i> |
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INFORMATION DISCLOSURE CITATION

Form PTO-1449 (Modified)

(Use several sheets if necessary)

ATTY. DOCKET NO.
023070-138122USSERIAL NO.
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Applicant: GERMAN, Michael S.

FILING DATE
December 11, 2003GROUP
To be assigned

U.S. PATENT DOCUMENTS

| Examiner Initial | | Document Number | Date | Name | Class | Subclass | Filing Date If Appropriate |
|---------------------|----|-----------------|----------|------------------|-------|----------|-------------------------------|
| 1.P. | AA | 4,394,443 | 07/19/83 | Weissman, et al. | 435 | 6 | 12/18/80 |
| | AB | 4,683,195 | 07/28/87 | Mollis, et al. | 435 | 6 | 02/07/86 |
| | AC | 4,683,202 | 07/28/87 | Mollis | 435 | 91 | 10/25/85 |
| | AD | 4,703,008 | 10/27/87 | Lin | C12N | 5/00 | 11/30/84 |
| | AE | 4,861,719 | 08/29/89 | Miller, et al. | 435 | 236 | 04/25/86 |
| | AF | 5,139,941 | 08/18/92 | Muzyczka, et al. | 435 | 172.3 | 10/25/91 |
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| | AH | 5,240,846 | 08/31/93 | Collins, et al. | 435 | 240.1 | 09/18/90 |
| | AI | 5,292,662 | 03/08/94 | Sandmeyer | 435 | 320.1 | 06/08/92 |
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| | AM | 5,589,466 | 12/31/96 | Felgner, et al. | A61K | 48/00 | 01/26/95 |
| 1.P. | AN | 6,004,944 | 12/21/99 | Rothman, et al. | A61K | 48/00 | 10/02/97 |

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| | | Document Number | Date | Country | Class | Subclass | Translation | |
|------|----|-----------------|----------|---------|-------|----------|-------------|----|
| | | | | | | | Yes | No |
| 1.P. | AO | WO 94/26915 | 11/24/94 | PCT | C12N | 15/86 | | XX |
| 1.P. | AP | WO 99/17610 | 11/15/99 | PCT | C12N | 13/00 | | XX |

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

| | | | | | | | | |
|------|----|---|--|--|--|--|--|--|
| 1.P. | AQ | Amsterdam, et al., "Studies on Dispersed Pancreatic Exocrine Cells," <i>J. Cell. Biol.</i> , 63:1057-1073 (1974). | | | | | | |
| 1.P. | AR | Avery, et al., "Studies on the Chemical Nature of the Substance Inducing Transformation of Pneumococcal Types," <i>J. Exp. Med.</i> , 174:137-158 (1994). | | | | | | |
| 1.P. | AS | Baum, "Advances in Salivary and Soft Tissue Management," <i>IADA</i> , 125:26S-30S (1994). | | | | | | |

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| EXAMINER <i>Deane PDM</i> | DATE CONSIDERED <i>10/12/05</i> |
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Form PTO-1449 (Modified)

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ATTY. DOCKET NO.
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Applicant: GERMAN, Michael S.

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December 11, 2003GROUP
To be assigned

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

| | | |
|------|----|---|
| 1.P. | AT | Boshart, et al., "A Very Strong Enhancer is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus," <i>Cell</i> , 41:521-520 (1985). |
| | AU | Brody, et al., "Adenovirus-Mediated <i>In Vivo</i> Gene Transfer," <i>NY Acad. Sci.</i> , 716:90-101 (1994). |
| | AV | Cockell, et al., "Identification of a Cell-Specific DNA-Binding Activity that Interacts with a Transcriptional Activator of Genes Expressed in the Acinar Pancreas," <i>Mol. Cell. Biol.</i> , 9:2464-2476 (1989). |
| | AW | Coghlan, "Gene Dream Fades Away," <i>New Scientist</i> , (Nov. 1995):14-15. |
| | AX | Crystal, "Transfer of Genes to Humans: Early Lessons and Obstacles to Success," <i>Science</i> , 270:404-410 (1995). |
| | AY | Elango, et al., "Molecular Cloning and Characterization of Six Genes, Determination of Gene Order and Intergenic Sequences and Leader Sequence of Mumps Virus," <i>J. Gen. Virol.</i> , 69:2893-2900 (1988). |
| | AZ | Felgner, et al., "Lipofection: A Highly Efficient, Lipid-Mediated DNA-Transfection Procedure," <i>Proc. Nat'l. Acad. Sci. USA</i> , 84:7413-7417 (1987). |
| | BA | Fynan, et al., "DNA Vaccines: Protective Immunizations by Parenteral, Mucosal, and Gene-Gun Inoculations," <i>Proc. Nat'l. Acad. Sci. USA</i> , 90:11478-11482 (1993). |
| | BB | Gerrard, et al., "Towards Gene Therapy for Haemophilia B Using Primary Human Keratinocytes," <i>Nat. Genet.</i> , 3:180 (1993). |
| | BC | Gitschier, et al., "Characterization of the Human Factor VIII Gene," <i>Nature</i> , 312:326-330 (1984). |
| | BD | Gorman, et al., "The Rous Sarcoma Virus Long Terminal Repeat is a Strong Promoter when Introduced into a Variety of Eukaryotic Cells by DNA-Mediated Transfection," <i>Proc. Nat'l. Acad. Sci. USA</i> , 79:6777-6781 (1982). |
| | BE | Grendell, et al., "Effect of Changes in Circulating Amylase Levels on Amylase Output in Bile," <i>The American Physiological Society</i> , G54-G59 (1982). |
| | BF | Groot, et al., "The Human α -Amylase Multigene Family Consists of Haplotypes with Variable Numbers of Genes," <i>Genomics</i> , 5:29-42 (1989). |
| | BG | Gunzberg, et al., "Virus vector design in gene therapy," <i>Molecular Medicine Today</i> 410-417 (1995). |
| | BH | Hagenbuehle, et al., "Expression of Mausy Amy-2 ⁺ Alpha-Amylase Genes is Regulated by Strong Pancreas-Specific Promoters," <i>J. Mol. Biol.</i> , 185:285-293 (1985). |
| 1.P. | BI | Hewitt, et al., "Human Gastric Intrinsic Factor: Characterization of cDNA and Genomic Clones and Localization to Human Chromosome 11," <i>Genomics</i> , 10:432-440 (1991). |

EXAMINER

Deanna P. M.

DATE CONSIDERED

10/12/05

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Form PTO-1449 (Modified)

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OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

| | | |
|-----|----|--|
| 1.0 | BJ | Jones, et al., "A Salivary Amylase Transgene is Efficiently Expressed in Liver but Not in Parotid Gland of Transgenic Mice," <i>Nucleic Acid Res.</i> , 17(6):6613-6623 (1989). |
| | BK | Korman, et al., "Expression of Human Class II Major Histocompatibility Complex Antigens Using Retrovirus Vectors," <i>Proc. Nat'l. Acad. Sci. USA</i> , 84:2150-2154 (1987). |
| | BL | Kozarsky, et al., "Adenovirus-Mediated Correction of the Genetic Defect in Hepatocytes from Patients with Familial Hypercholesterolemia," <i>Somat. Cell Mol. Genet.</i> , 19(5):449-458 (1993). |
| | BM | Kwano, et al., "Complete Nucleotide Sequence of the Matrix Gene of Human Parainfluenza Typ 2 Virus and Expression of the M Protein in Bacteria," <i>Viol.</i> , 179:857-861 (1990). |
| | BN | Ledley, "Nonviral gene therapy: the promise of genes as pharmaceutical products," <i>Human Gene Therapy</i> , 6:1129-1144 (1995). |
| | BO | Lowry, et al., "Protein Measurement with the Folin Phenol Reagent," <i>J. Biol. Chem.</i> , 193:265-275 (1951). |
| | BP | Maeda, et al., "Adenovirus-Mediated Transfer of Human Lipase Complementary DNA to the Gallbladder," <i>Gastroenterology</i> , 106:1638-1644 (1994). |
| | BQ | Marshall, et al., "Less Hype, Mor Biology Needed for Gene Therapy," <i>Science</i> , 270:1751 (1995). |
| | BR | Marshall, "Gene Therapy's Growing Pains," <i>Science</i> , 269(5227):1050 (1995). |
| | BS | Martial, et al., "Human Growth Hormone: Complementary DNA Cloning and Expression in Bacteria," <i>Biotechnology</i> , 24:293-298 (1992). |
| | BT | Mastrangeli, et al., "Direct In Vivo Adenovirus-Mediated Gene Transfer to Salivary Glands," <i>Am. J. Physiol.</i> , 266:(6, part 1):G1146-55 (1994). |
| | BU | Mastrangelo, et al., "Gene Therapy for Human Cancer: An Essay for Clinicians," <i>Seminars in Oncology</i> , 23:4-21 (1996). |
| | BV | Miller, et al., "Targeted Vectors for Gene Therapy," <i>FASEB J.</i> , 9(2):190-199 (1995). |
| | BW | Miyasaka, et al., "Endocrine Secretion of α -Amylase by the Process by the Pancreas," <i>American Physiological Society</i> , G170-G175 (1981). |
| | BX | Morgan, et al., "Expression of an Exogenous Growth Hormone Gene by Transplantable Human Epidermal Cells," <i>Science</i> , 237:1476-1479 (1987). |
| | BY | Morsy, et al., "Progress Toward Human Gene Therapy," <i>JAMA</i> , 270:2338-2345 (1993). |
| | BZ | Mulligan, "The Basic Science of Gene Therapy," <i>Science</i> , 260:926-932 (1993). |
| | CA | Newgard, et al., "Molecular Engineering of the Pancreatic β -Cell," <i>J. Lab. Clin. Med.</i> , 122(4):356-363 (1993). |
| 1.0 | CB | Orkin, et al., "Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy," December 7, 1995. |

EXAMINER

Debra P. No

DATE CONSIDERED

10/12/05

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OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

| | | |
|------|----|--|
| J.P. | CC | Pittet, et al., "Mouse Alpha-Amylase Loci, Amy-2 ^a and Amy-1 ^a , are Closely Linked," <i>J. Mol. Biol.</i> , 182:359-365 (1985). |
| | CD | Ramakrishna, et al., "Gene Therapy for Exocrine Pancreatic Insufficiency," <i>Gastroenterology</i> , 106(6):1711-1713 (1994). |
| | CE | Robins, et al., "Retrotransposons and the Evolution of Mammalian Gene Expression," <i>Genetica</i> , 86:191-201 (1992). |
| | CF | Rosenfeld, et al., "Adenovirus-Mediated Transfer of a Recombinant α -Antitrypsin Gene to the Lung Epithelium In Vivo," <i>Science</i> , 252:431-434 (1991). |
| | CG | Rosenfeld, et al., "In Vivo Transfer of the Human Cystic Fibrosis Transmembrane Conductance Regulator Gene to the Airway Epithelium," <i>Cell</i> , 68:143-155 (1992). |
| | CH | Samara, et al., "Molecular Biology and Therapy of Disease," <i>The American Journal of Surgery</i> , 165:720-727 (1993). |
| | CI | Samuelson, et al., "Expression of the Human Amylase Genes: Recent Origin of a Salivary Amylase Promoter from an Actin Pseudogene," <i>Nucleic Acids Res.</i> , 16:8261-8276 (1988). |
| | CJ | Schibler, et al., "Structural Arrangement of and Tissue-Specific Expression of the Two Murine Alpha-Amylase Loci Amy-1 and Amy-2," <i>Oxf. Surv. Eukaryot. Genes</i> , 3:210-234 (1986). |
| | CK | Sierra, et al., "Different Tissue-Specific Expression of the Amylase Gene Amy-1 in Mice and Rats," <i>Mol. Cell. Biol.</i> , 6(11):4067-4076 (1986). |
| | CL | Stewart, et al., "Insulin Delivery by Somatic Cell Gene Therapy," <i>J. Mol. Endocrinol.</i> , 11(3):335-341 (1993). |
| | CM | Stewart, et al., "Insulin-Releasing Pituitary Cells as a Model for Somatic Cell Gene Therapy," <i>J. Mol. Endocrinol.</i> , 143:339-343 (1994). |
| | CN | Suggs, et al., "Use of Synthetic Oligonucleotides as Hybridization Probes: Isolation of Cloned cDNA Sequences for Human β 2-Microglobulin," |
| | CO | Takeuchi, et al., "In Vitro Transcription and Replication of the Mumps Virus Genome," <i>Archiv. Virol.</i> , 128:177-183 (1993). |
| | CP | Tanabayashi, et al., "Expression of Mumps Virus Glycoproteins in Mammalian Cells from Cloned cDNA's: Both F and HN Proteins are Required for Cell Fusion," <i>Virol.</i> , 187:801-804 (1992). |
| | CQ | Tanabayashi, et al., "Identification of an Amino Acid that Defines the Fusogenicity of Mumps Virus," <i>J. Virol.</i> , 67:2928-2931 (1993). |
| J.P. | CR | Ting, et al., "Endogenous Retroviral Sequences are Required for Tissue-Specific Expression for a Human Salivary Amylase Gland," <i>Genes Dev.</i> , 6:1457-1465 (1992). |

EXAMINER

Sharon P. [Signature]

DATE CONSIDERED

10/12/08

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GROUP
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OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

| | | |
|------|----|--|
| 1.P. | CS | Tomita, et al., "A Novel Type of Human α -Amylase Produced in Lung Carcinoid Tumor," <i>Gene</i> , 76:11-18 (1989). |
| | CT | Towbin, et al., "Electrophoretic Transfer of Proteins from Polyacrylamide Gels to Nitrocellulose Sheets: Procedure and Some Applications," <i>Proc. Nat'l. Acad. Sci. USA</i> , 76:4350-4354 (1979). |
| | CU | Wolff, et al., "Direct Gene Transfer into Mouse Muscle In Vivo," <i>Science</i> , 247:1465-1468 (1990). |
| | CV | Wood, et al., "Expression of Active Human Factor VIII from Recombinant DNA Clones," <i>Nature</i> , 312:330-337 (1984). |
| | CW | Yang, et al., "In Vivo and In Vitro Gene Transfer to Mammalian Somatic Cells by Particle Bombardment," <i>Proc. Nat'l. Acad. Sci. USA</i> , 87:9568-9572 (1990). |
| | CX | Taniguchi, et al., "Constant delivery of proinsulin by encapsulation of transfected cells," <i>J. Surgical Res.</i> , 70:41-45 (1997). |
| | CY | Adesanya, et al., "Immediate Inflammatory Responses to Adenovirus-Mediated Gene Transfer in Rat Salivary Glands," <i>Human Gene Therapy</i> , 7:1085-1093 (June 10, 1996). |
| | CZ | Barka, et al., "Retrovirus-Mediated Gene Transfer into Salivary Glands In Vivo," <i>Human Gene Therapy</i> , 7:613-618 (March 20, 1996). |
| | DA | Buckel, et al., "Recombinant proteins for therapy," <i>TIPS</i> , 17:450 (1996). |
| | DB | Curiel, et al., "Gene transfer to respiratory epithelial cells via the receptor-mediated endocytosis pathway," <i>Am. J. Respir. Cell. Mol. Biol.</i> , 6(3):247-252 (1992). |
| | DC | Friedmann, "Human gene therapy--an immature genie, but certainly out of the bottle," <i>Nature Med.</i> , 2:144 (1996). |
| | DD | Geokas, et al., "Molecular forms of immunoreactive pancreatic elastase in canine pancreatic and peripheral blood," <i>Am. J. Physiol.</i> , 238:238-246 (1980). |
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| 1, P | DH | Kolodka, et al., "Gene Therapy for Diabetes in Mellitus in Rats by Hepatic Expression of Insulin," <i>Proc. Nat'l. Acad. Sci. U.S.A.</i> , 92:3293-3297 (April, 1995). |
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